JAN 2 9 2004

Pac-Dent International (Suzhou), Inc.

K033120

510(k) Summary of Safety and Effectiveness

Submitter:

Pac-Dent International (Suzhou), Inc.
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Jiangsu Province, P. R. China
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Contact Person: Xu Wang
US Agent
Daniel Wang
Phone: 909-839-0888
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Date Summary Prepared: Sep.2003

Device Name:

Trade Name: ScaleTron™ Piezo Ultrasonic Scaler
Common Name: Piezo Ultrasonic Scaler
Classification Name: Scaler, Ultrasonic
Classification: Class II

Devices for Which Substantial Equivalence is Claimed:

Deldent Ltd. Delsonic 2000™

Device Description:

The Scaletron ™ consists of the main scaler unit (including a peristaltic water pump), a hose, a connector for handpiece and a foot control switch. It is designed to generate regular linear tip movement at nominal 30 KHz.

Intended Use of the Device:

The Scaletron ™ is a Piezo Ultrasonic Scaler intended for use in fast and reliable removal of light to heavy calculus deposits and stains from teeth.

Substantial Equivalence:

Scaletron™ Piezo Ultrasonic Scaler is substantially equivalent to the other legally marketed devices in the United States. Scaletron™ Piezo Ultrasonic Scaler functions in a same manner and is intended for the same use as the Delsonic 2000™ Piezo Ultrasonic Scaler (K014238) designed by Deldent Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2004

Pac-Dent International (SUZHOU), limited
C/O Mr. Daniel Wang
President
Pac-Dent Interantional, Incorporated
21078 Commerce Pointe Drive
Walnut, California 91789

Re: K033120
Trade/Device Name: SacleTron Piezo Ultrasonic Scaler
Regulation Number: 21 CFR 872.4850
Regulation Name: Ulatrasonic Sacler
Regulatory Class: II
Product Code: ELC
Dated: January 7, 2004
Received: January 8, 2004

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph., D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033120

Device Name: ScaleTron™ Piezo Ultrasonic Scaler

Indications for Use:

The Scaletron™ is a Piezo Ultrasonic Scaler intended for use in fast and reliable removal of light to heavy calculus deposits and stains from teeth.

Prescription Use x AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033120